

REMARKS

Claims 15-20, 23, 25-32 and 42-44 remain pending in this application.

By way of review, the presently claimed invention relates to:

A valve for implantation at a desired location within a mammal, comprising:

a flexible sleeve having a proximal end, a distal end and an outside surface;

at least one cusp secured to the sleeve and configured to permit blood flow through the at least one cusp in a single direction;

at least one ring attached to the outside surface at only the proximal end of the sleeve, the at least one ring being attached to a portion of the sleeve that is not everted, wherein the ring is expandable from a first diameter to a larger, second diameter; and

at least one fastener connected to the at least one ring, the at least one fastener extending in a direction radially outward with respect to the sleeve and including at least one leg.

The Examiner has rejected claims 15-20, 23, 25-32 and 42-44 under 35 USC §103 as being unpatentable over Ersek USPN 3,657,744 in view of Lazarus et al USPN 5,562,728.

Ersek was cited by the Examiner for :

.....disclos(ing) the invention as substantially as claimed being a valve comprising a flexible sleeve (the outer portion of the valve sutured to the support) having 3 cups 46 and a balloon expandable ring attached to the outside of its proximal end wherein the sleeve is not inverted shown best in figures 4 and 8. In regard to the ring, Ersek discloses a plurality of zigzag shaped support rings that each are shorter than the length of the sleeve. Ersek further discloses that the heart valve can be positioned at a variety of positions at the end of the device. This would allow one zigzag portion to be positioned according to the applicant's invention.

While the Examiner acknowledges that the Ersek does not disclose at least one fastener leg, Applicants also note that Ersek is distinguishable in that it discloses rings at both the proximal and distal ends for the devices (Ersek, Figs. 4 and 8) compared with Applicants only having *at least one ring attached to the outside surface at only the proximal end of the sleeve*.

Lazarus was cited by the Examiner for:

.....teaching the use of a support comprising a plurality of fasteners 151 attached to a zigzag shaped ring comprising a pair of legs having sharp ends (Figures 11-13) in the same field of endeavor for the purpose of piercing and anchoring the device into the surrounding tissue.

The Examiner then concludes that it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the fasteners taught by Lazarus with the device of Ersek in order to provide better attachment to the implant site.

This rejection is respectfully traversed as it appears that the Examiner has arrived at the Applicants' invention through hindsight reconstruction from the prior art. In the current instance, the Examiner selectively combines securing rings that are externally mounted to a device (Ersek) with those internally mounted to a device (Lazarus). Furthermore, the Examiner cites only references that disclose securing rings that are attached to both the proximal and distal ends of the devices (Ersek and Lazarus) while Applicant clearly requires the securing ring at the proximal end of the device. While the Examiner concludes that it would have been obvious for one of ordinary skill to derive the relationships identified and claimed by Applicants, it also appears that the Examiner may be relying upon certain unsupported assertions to conclude that claims 15-20, 23, 25-32 and 42-44 are obvious over Ersek in view of Lazarus. Applicants note that the assertions appear to be Official Notices taken by the Examiner. Should this be the case, Applicants respectfully request evidence in support of the Official Notices, as provided for under MPEP § 2144.03, p. 2100-145 (Rev. 6, Sept. 2007). Therefore, the foregoing rejection is respectfully requested to be withdrawn.

Serial No. 10/047581

Applicants grant the PTO permission to charge the Deposit Account No. 10-0750/TJS/HRT0287 for any fees or charges related to this application. Applicants respectfully request the Examiner to contact the below-signed if a discussion regarding the merits would advance prosecution of this case.

Respectfully submitted,

By: Theodore J. Shatynski/
Theodore J. Shatynski
Reg. No. 36,676

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2498
Date: October 11, 2010